REMARKS

The above claim amendments are submitted along with the following remarks to be fully responsive to the outstanding Office Action mailed November 21, 2005. It is further submitted that this response is timely filed within the three month shortened statutory period. Reconsideration of all outstanding grounds of objection and rejection and allowance of the subject application are respectfully requested.

Claims 21-29 have been rejected under obviousness-type double patenting with respect to claims 4-7 of commonly owned, U.S. Patent No. 6,652,814 (hereinafter referred to as "the '814 patent"). That paragraph of the Office Action further refers to a force range presented in claim 3; however, because that claim depends from independent claim 1, which is not the subject of the double patenting rejection, it is believed that this rejection may have been a typographical error. In any case, in the rejection, the Examiner stated that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other." It is submitted that the presently claimed invention is patentably distinct over the claims of the '814 patent for at least the following reasons.

The presently claimed system for determining an aspect of a biological fluid of independent claim 21 sets out a system including a test strip meter, at least one test strip comprising a sample port, a channel, a measurement area, and a compressible bladder, and a test strip holder for use with the meter and the at least one test strip, wherein the holder comprises a lip for forming a liquid seal with a first surface of the test strip when the test strip is received within the test strip holder, and wherein the holder comprises a support that, along with the lip, defines an opening in the test strip holder. Independent claim 4 of the '814 patent includes a test strip meter system including a test strip meter and a test strip holder, wherein the test strip holder comprises a support for receiving a test strip, a lip associated with that support, and a raised bump on the support that contacts the bottom of a test strip inserted into an opening of the holder. This claim includes further limitations on the lip and the raised bump; however, claim 4 does not suggest the use of a test strip comprising a bladder, nor any of the other test strip features set out above relative to claim 21. Thus, claim 4 of the '814 neither meets nor suggests all of the limitations of the present claim 21.

In addition, dependent claims 5-6 of the '814 patent include a strip holder that is readily removable from the meter and a test strip inserted into the opening of the strip holder, respectively, and claim 3, which depends from claim 1, sets out a range of applied forces. However, none of these claims specifically suggest the use of a test strip comprising a bladder or any of the other test strip limitations. In this regard, no further reference is cited to cure this deficiency. Finally, claim 7 of the '814 patent is directed to a method of using a test strip meter which also does not suggest the use of a test strip having a bladder. Accordingly, it is submitted that independent claim 21 of the subject application and its dependent claims 22-29 include a specific test strip limitation that makes these claims patentably distinct from claims 3-7 of the '814 patent, and as such, it is respectfully requested that the obviousness-type double patenting rejection be withdrawn relative to claims 21-29.

Claims 21-24, 29, 31, 32, and 34 were rejected under 35 U.S.C. § 102(b) as anticipated by Gassenhuber (U.S. Patent No. 4,934,817). Applicants respectfully disagree. As amended, claim 21 recites a test strip meter, at least one test strip, a test strip holder, and a bladder actuator. The at least one test strip comprises a sample port, a channel, a measurement area, and a compressible bladder for creating a suction force to draw a biological fluid sample through the channel from the sample port to the measurement area. The bladder actuator is provided for compressing the bladder of a test strip when it is received in the test strip holder. This description of the test strip and bladder actuator is supported throughout the originally submitted application, such as on page 6, line 15 through page 7, line 8, and on page 9, line 27 through page 10, line 15, which sections describe these test strips as being used with the test strip systems and methods of the invention. Thus, no new matter is added. The test strip holder also includes a lip for forming a liquid seal with a first surface of the test strip.

In contrast, Gassenhuber discloses a test strip holder including a U-shaped support part 34 having a cross-piece support plate 38 and a U-shaped pressing element 40 having a cross piece 44 arranged inside a U-shaped support part (see col. 3, for example). In use, a test strip can be inserted such that a test field area thereof is positioned between the support plate 38 and the cross piece 44 of pressing element 40. Actuation of a cam 64 causes the test field to be pressed flat against the underside of support plate 38. However,

Gassenhuber does not disclose any holder opening including a lip at all, and further does not disclose any lip or similar structure for forming a liquid seal with a first surface of a test strip. In fact, Gassenhuber provides only for positioning of the test strip in a "well-defined position relative to the measuring optical system 70, 72 and 74" (col. 4, lines 34-35), which does not in any way suggest a liquid seal. With regard to the statement in the Office Action that the placement of a test strip in a holder between elements 34 and 44 causes engagement between these surfaces and a test strip in a sealing manner, there is no disclosure in Gassenhuber that such a contact between surfaces would constitute any type of sealing contact, and does not disclose any reason to form a liquid seal between any of these surfaces. Further, Gassenhuber does not disclose that its test strip has a compressible bladder and consequently does not disclose any bladder actuator mechanism or path for fluid from a sample port to a measurement area of a test strip. Thus, claim 21 is believed allowable, along with claims 22-24 and 29, which depend therefrom.

With regard to claims 31, 32, and 34, which are directed to a method of determining at least one aspect of a biological sample, these claims are similarly allowable over Gassenhuber at least in that Gassenhuber lacks the disclosure of a test strip with a compressible bladder, and therefore also lacks the disclosure of bladder actuation steps. Futher, Gassenhuber does not disclose the application of substantially equal and opposing forces to first and second surfaces of a test strip, as in the present claim 31. Thus, withdrawal of the rejection of claim 31, along with its dependent claims 32 and 34, is respectfully requested.

Claims 21-24, 29, 31, 32, and 34 were also rejected under 35 U.S.C. § 102(e) as anticipated by Douglas et al. (U.S. Patent No. 6,106,780). Again, Applicants respectfully disagree. As first indicated by the Examiner, the system of Douglas et al. includes a test strip 11, which includes a top surface and bottom surface 15, as shown, for example, in Fig. 1A. Between these top and bottom surfaces is a test pad 12 and a holder 13. The analyte concentration of a sample applied to the test pad may be read through an opening in the bottom surface 15. However, the Examiner then states that the test strip 11 itself may be characterized as a test strip holder, presumably because a test pad is in some manner associated therewith. Applicants disagree with this characterization in that it is

contrary to the disclosure of Douglas et al., which specifically defines the test strip in the manner discussed above (i.e., a test surface body having a top surface and bottom surface 15, test pad 12, and holder 13). In other words, the test pad 12 cannot also be referred to as "the test strip", since this would be contrary to the teachings of Douglas et al.

Further, even if the test strip 11 could possibly be considered to be a test strip holder as suggested by the Examiner (again, a contention with which Applicants disagree), Douglas et al. still cannot anticipate claim 21 of the present invention. In particular, Douglas et al. do not disclose any structure that can be considered to be a lip that forms a liquid seal with a test strip 11, a holder 13, or any other structure thereof. In fact, Figures 1A and 1B, and the descriptions thereof, clearly do not show any lip structure for forming a liquid seal that is associated with either the test strip 11, the holder 13, or any openings of either of these. In other words, there is no disclosure in Douglas et al. that holder 13 blocks liquid. We further note that holder 13 does provide the functions of providing a means to position the test pad 12 relative to the sensors 45 and providing a means to block ambient light, but that neither of these functions suggest providing a liquid seal. Further, Douglas et al. do not disclose that their test strip has a compressible bladder and consequently also do not disclose any bladder actuator mechanism or path for fluid from a sample port to a measurement area of a test strip. Thus, claim 21 is believed allowable, along with claims 22-24 and 29, which depend therefrom.

With regard to claims 31, 32, and 34, which are directed to a method of determining at least one aspect of a biological sample, these claims are similarly allowable over Douglas et al. at least in that Douglas et al. lacks the disclosure of a test strip with a compressible bladder, and therefore also lacks the disclosure of bladder actuation steps. Thus, withdrawal of the rejection of claims 31, 32, and 34 is respectfully requested.

Claims 25-28, 35, and 36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Gassenhuber in view of Hones et al. (U.S. Patent No. 5,424,035). Hones et al. is cited for its use of a stationary pressure element, which does nothing to overcome the deficiencies of Gassenhuber set out above relative to independent claims 21

or 31. Thus, claims 25-28, 35, and 36 are believed allowable over Gassenhuber in view of Hones et al.

Claim 33 was rejected under 35 U.S.C. § 103(a) as unpatentable over Douglas et al. in view of Anderson et al. (6,066,243). Anderson et al. is cited for its disclosure of measuring clotting times, which does nothing to overcome the deficiencies set out above to independent claim 31, from which claim 33 depends. Thus, claim 33 is believed allowable over Douglas et al. in view of Anderson et al.

Accordingly, it is submitted that presently pending claims 21-36 are currently in condition for allowance, a notice of which is earnestly solicited. The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

The Commissioner is authorized to charge any additional fees or credit any overpayment to Kagan Binder deposit account No. 50-1775 and notify us of the same.

Respectfully Submitted,

Dated: 2/21/06 By

Michaele A. Hakamaki, Reg. No. 40,011
Customer Number 33072
Phone: 651-275-9839
Facsimile: 651-351-2954

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